Section 6
510(k) Summary

Submission Date: April 25, 2008

Submitter Information:

Company Name: TraumaCure, Inc.

Company Address: 7735 Old Georgetown Road
Suite 1200
Bethesda, MD 20814

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President and Chief Operating Officer
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Device Information:

Trade Name: WoundStat™

Common Name: Wound Dressing

Device Class: Unclassified

Predicate Device: **WoundStat™**
TraumaCure, Inc.
K071936

Intended Use: WoundStat™ is intended for use in emergency wound management.

Indications for Use: WoundStat™ wound dressing for OTC is indicated for temporary external use to control bleeding from minor cuts and abrasions of the skin.

Device Description:

WoundStat™ is a clay-based, granular hemostatic agent that is poured on a moderate to severe wound and held in place until it adheres to the wound and hemostasis is achieved. The device is packaged in a foil package and is provided sterile.

WoundStat™ was developed to address an unmet need in battlefield, ballistic, and traumatic injuries. A similar need exists in rural areas where there is a delay in obtaining medical care. For example, traumatic injuries can be sustained in manufacturing, construction, farming, and outdoor activities such as hunting and rock climbing. Uncontrolled hemorrhage continues to be a leading cause of death in both the military and in civilian populations under 35 years of age. The primary issue in these deaths is uncontrolled hemorrhage. OTC availability of WoundStat™ is consistent with numerous other legally marketed OTC wound management devices, such as QuikClot Sport™ (K070010), MedTrade Products CELOX Topical Hemostatic Granules OTC (K061079), BleedArrest™ (K070211), and BloodStop (K071578). It should be noted that WoundStat™ cleared for Rx use (K071936) was determined to be substantially equivalent to QuikClot® (K013390), a prescription device now cleared as QuikClot Sport™ (K070010) for OTC use.

Comparison to Predicate Device:

WoundStat™ for OTC use is highly similar to WoundStat™ cleared for Rx use (K071936). The mechanism of action and the indications for use in emergency wound management are unchanged. The intended use has been modified, from Rx use to OTC use, and the labeling has been revised in conformance with 21 CFR 801 Subpart C.

WoundStat™ for Rx use has been previously demonstrated to be as safe and effective as marketed wound management devices (K071936). New labeling has been developed for the OTC device, in conformance with 21 CFR 801 Subpart C and modeled after legally marketed OTC wound management devices, including QuikClot Sport™ (K070010), MedTrade Products CELOX Topical Hemostatic Granules OTC (K061079), BleedArrest™ (K070211), and BloodStop (K071578).

Conclusion:

WoundStat™ for OTC use is as safe and effective as the WoundStat™ for Rx use described in 510(k) K071936. Therefore, WoundStat™ for OTC use is substantially equivalent, should be regulated by FDA within the same generic type of device that includes the cited predicate, and should be cleared for marketing in the United States (US).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2008

Traumacure, Inc.
% Becker & Associates Consulting, Inc.
Campbell T. Hutton, MSPH
2001 Pennsylvania NW, Suite 950
Washington, District of Columbia 20006

Re: K081183
Trade Name: WoundStat™
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 5, 2008
Received: June 6, 2008

Dear Campbell Hutton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5
Indications for Use Statement

510(k) Number (if known): k081183

Device Name: WoundStat™

Indications for Use:

WoundStat™ wound dressing for OTC is indicated for temporary external use to control bleeding from minor cuts and abrasions of the skin.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081183